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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TOWA, RENE T	
ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,933	PARINS ET AL.	
	Examiner	Art Unit	
	RENE TOWA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-15,17-54 and 61-67* is/are pending in the application.

4a) Of the above claim(s) *23-54,61 and 62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-15,17-22 and 63-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to an amendment filed May 9, 2008. Claims 1, 3-4, 6-15, 17-54 & 61-67 are pending. Claims 2, 5, 16 & 55-60 have been cancelled. Claims 23-54 & 61-62 have been withdrawn. New claims 63-67 have been added. Claims 1, 14 & 21 have been amended.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. **Claims 1, 3-4, 12-15, 17, 22 & 63-67** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonello et al. (US 4,732,163) in view of Gambale (US 5,063,935).

In regards to **claim 1**, Bonello et al. discloses a guidewire, comprising:

a core member 1 having a proximal end and a distal end;

a tubular member 3 having a proximal end and a distal end and a lumen therebetween, the tubular member 3 disposed about and connected to the distal end of the core member 1, the distal end of the tubular member 3 extending distally beyond the distal end of the core member 1; and

a coil member 2 connected to and disposed about the tubular member 3;

wherein the coil member 2 includes a distal end and a proximal end, and wherein the distal end of the coil member 2 extends distally beyond the distal end of the tubular member 3 (see figs. 1-2).

In regards to **claim 3**, Bonello et al. discloses a guidewire wherein the proximal end of the coil member 2 is positioned distal of the distal end of the core member 1 (see figs. 1-2).

In regards to **claim 12**, Bonello et al. discloses a guidewire wherein the tubular member 3 has a hemispherical cross section (see figs. 1-2).

In regards to **claim 13**, Bonello et al. discloses a guidewire wherein the tubular member 3 has a circular cross section (see figs. 1-2).

In regards to **claim 14**, Bonello et al. discloses a guidewire comprising:

a core member 1 including a proximal portion having a proximal end and a distal portion having a distal end; and

a distal assembly (2, 3) including a tubular member **3 having an outer surface adapted for connection to the distal portion of the core member** 1, and an outer surface, and a coil member 2 connected to the tubular member 3;

wherein the distal assembly (2, 3) is connected to the distal portion of the core member 1 such that a portion of the distal assembly extends distally beyond the distal end of the core member 1 (see figs. 1-2).

In regards to **claim 15**, Bonello et al. discloses a guidewire wherein the distal assembly is connected to the distal portion of the core member 1 such that a portion of the tubular member 3 extends distally beyond the distal end of the core member 1 (see figs. 1-2).

In regards to **claim 17**, Bonello et al. discloses a guidewire further including a polymer sheath disposed about the coil member 2, the tubular member 3, and at least a portion of the core member 1 (see figs. 1-2).

In regards to **claim 22**, Bonello et al. discloses a guidewire wherein the tubular member 3 has a circular cross section (see figs. 1-2).

In regards to **claim 63**, Bonello et al. discloses a medical device wherein the proximal end of the coil 2 is distal to the distal end of the core member 1 (see figs. 1-2).

In regards to **claim 64**, Bonello et al. discloses a medical device wherein the proximal end of the coil 2 is distal to the distal end of the tubular member 3 (see figs. 1-2).

In regards to **claim 65**, Bonello et al. discloses a guidewire wherein the proximal end of the coil 2 is distal to the distal end of the core member 1 (see figs. 1-2).

In regards to **claim 66**, Bonello et al. discloses a guidewire wherein the proximal end of the coil 2 is distal to the distal end of the tubular member 3 (see figs. 1-2).

In regards to **claim 67**, Bonello et al. discloses a guidewire, comprising:

a core member 1 having a proximal end and a distal end;

a tubular member 3 having a proximal end and a distal end, the tubular member 3 disposed about and connected to the distal end of the core member 1, the distal end of the tubular member 3 extending distally beyond the distal end of the core member 1; and

a metallic coil member 2 disposed about and attached to the distal end of the tubular member 3; and

wherein the distal end of the tubular member 3 extends distally beyond the distal end of the core member 1 and the coil member 2 extends distally beyond the distal end of the tubular member 3 (see figs. 1-2).

Bonello et al. disclose a guidewire, as described above, that fails to explicitly teach a metallic core member and a metallic tubular member such that the distal end of the core member has a diameter that is less than the inner diameter of the tubular member.

However, **Gambale** discloses a guidewire comprising a metallic core member 10, a tubular member 26, and a coil member 14 such that the distal end of the core member 10 has a diameter that is less than the inner diameter of the tubular member 26 (see figure; see col. 2, lines 60-68).

In regards to ***claims 1, 4, 14 & 67***, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the guidewire of Bonello et al. to include a tubular member that fits over the distal end of the core member as taught by Gambale in order to externally fix the tubular member to the core member such that the core member serves as a bearing surface to the tubular member. Furthermore, it has previously been held that merely shifting location of parts (i.e. location of the joint) is not patentable--*See In re Japikse, 181 F. 2d 1019, 1023, 86 USPQ 70, 73 (CCPA 1950).*

Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the guidewire of Bonello et al. to include a tubular member that is metallic as taught by Gambale in order to achieve a fluoroscopic image that is darker at the junction between the tubular member and the coil member (see Gambale, col. 2, lines 60-68).

Similarly, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guidewire of Bonello et al. with a metallic core member as claimed in order to achieve a core member that is resilient yet steerable and torqueable through tight vasculature bends.

4. **Claims 6-7** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonello et al. ('163) in view of Gambale ('935), and further in view of Richardson et al. (US 6,673,025).

Bonello et al. as modified by Gambale disclose a guidewire, as described above, that fails to explicitly teach a polymer sheath.

However, **Richardson et al.** discloses a guidewire comprising a polymer sheath 127 disposed over all of the core member 141 (see fig. 17; col. 14, lines 42-67; col. 15, lines 1-10).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guidewire of Bonello et al. as modified by Gambale with a polymer sheath as taught by Richardson et al. in order to increase the lubricity of the guidewire and/or achieve a guidewire that provides therapeutic, diagnostic or hydrophilic agent.

5. **Claim 8 is** rejected under 35 U.S.C. 103(a) as being unpatentable over Bonello et al. ('163) in view of Gambale ('935), and further in view of Palmer et al. (US 6,544,231).

Bonello et al. as modified by Gambale discloses a guidewire, as described above, that fails to teach the process of laser welding or soldering.

However, **Palmer et al.** disclose a medical instrument wherein a coil is bonded to a metallic tubular structure through laser welding (see column 4/lines 16-18).

Since it is known to provide metallic tubular and core members, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to attach the guidewire of Bonello et al. as modified by Gambale with a connecting process as taught by Palmer et al. in order to tightly fuse metal elements together.

6. **Claims 9-10 & 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonello et al. ('163) in view of Gambale ('935), and further in view of Cook et al. (US 5,213,111).

Bonello et al. as modified by Gambale discloses a guidewire, as described above, that fails to teach connecting the tubular member through crimping.

However, **Cook et al.** disclose a guidewire wherein a coil member 2 is connected to a core member through crimping (see column 3/lines 13-16).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guidewire of Bonello et al. as modified by Gambale with a connecting process as taught by Cook et al. in order to hold the elements together in a friction-fit fashion.

7. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Bonello et al. ('163) in view of Gambale ('935), Cook et al. ('111), and further in view of Palmer et al. (US 6,544,231).

Bonello et al. as modified by Gambale and Cook et al., above, discloses a guidewire, as described above, that fails to teach the process of laser welding or soldering.

However, **Palmer et al.** disclose a medical instrument wherein a coil is bonded to a metallic tubular structure through laser welding (see column 4/lines 16-18).

Since it is known to provide metallic tubular and core members, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to attach the guidewire of Bonello et al. as modified by Gambale and Cook et al., above, with a connecting process as taught by Palmer et al. in order to tightly fuse metal elements together.

8. **Claims 18 & 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonello et al. ('163) in view of Gambale ('935), and further in view of Palmer et al. (US 6,544,231).

Bonello et al. as modified by Gambale above, discloses a guidewire, as described above, that fails to teach the process of laser welding or soldering.

However, **Palmer et al.** disclose a medical instrument wherein a coil is bonded to a metallic tubular structure through laser welding (see column 4/lines 16-18).

Since it is known to provide metallic tubular and core members, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to attach the guidewire of Bonello et al. as modified by Gambale above, with a connecting process as taught by Palmer et al. in order to tightly fuse metal elements together.

9. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Bonello et al. ('163) in view of Gambale ('935), and further in view of Buchbinder et al. (US 4,815,478).

Bonello et al. as modified by Gambale above, discloses a guidewire, as described above, that fails to teach a guidewire wherein the tubular member comprises a C-shaped cross section.

However, **Buchbinder et al.** disclose a guidewire comprising a tubular member 41 wherein the tubular member 41 comprises a C-shaped cross section (see figs. 3-4).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the guidewire of Bonello et al. as modified by Gambale above to include a C-shaped cross section as taught by Buchbinder et al. in order to increase the flexibility of the guidewire in the distal direction for better steerability.

Response to Arguments

10. Applicant's arguments filed May 9, 2008 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/R. T./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736